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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/159,068	09/23/98	MARATOS-FLIER E	10276/014002

HM12/1020

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EXAMINER	
SAOUD, C	
ART UNIT	**PAPER NUMBER**
1647	9

DATE MAILED: 10/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/159,068	MARATOS-FLIER et al.
Examiner	**Group Art Unit**
Christine Saoud	1647

☒ Responsive to communication(s) filed on *Sep 11, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-29* is/are pending in the application.

Of the above, claim(s) *1-7 and 13-29* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *8-12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election without traverse of Group II in Paper No. 8 is acknowledged.

2. Claims 1-7 and 13-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Specification

4. The abstract of the disclosure is objected to because it is not a complete sentence and it does not reflect the claimed invention. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

> person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 8-12 are single means claims in that they recite "MCH antagonist", which is defined in the instant specification as "agents which result in an inhibition of feeding behavior" and includes "agents with significant amino acid homology to MCH as well as agents which are unrelated by amino acid sequence homology or which are not polypeptides" (see page 13 of the specification). MPEP 2164.08(a) defines a single means claim as a claim which covered every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in In re Hyatt , 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property (i.e. MCH antagonist), a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. This appears to be the instant case and the claims are not commensurate in scope with the specification. Applicant

should note that the claims encompass such things as drinking water or eating low calorie food due to the definition of "MCH antagonist" in the specification.

The instant specification fails to identify a single compound which is derived from MCH which acts as an antagonist and inhibits eating, appetite or gain of weight. The instant specification discloses that MCH promotes eating behavior. The specification indicates that MCH could be altered or modified in order to generate a compound which acts as an antagonist of MCH (see page 24 of the specification). However, one of ordinary skill in the art does not have a reasonable expectation that any one embodiment encompassed by the generic formula found in the specification would function in the manner required by the claims, absent evidence to the contrary. For example, at page 21 of the specification, it is stated that MCH(5-15) is sufficient to elicit a response equipotent to native MCH. Then, at page 26, MCH (5-16) is indicated to be an antagonist of MCH. This is inconsistent in that the specification indicates that the amino acid at position 16 is not required for activity of MCH, but then the specification further states that if it is present, the molecule will be an antagonist. Based on this disclosure, one of ordinary skill in the art would not know which forms of the modified MCH would act as an antagonist without first making and testing each possible mutant. Although the specification teaches which amino acids are critical for the biological activity of MCH, the disclosure as to which amino acids would be critical for antagonistic activity contradict these statements. Therefore, the specification does not provide clear guidance as to which amino acids (i.e. structural elements) of the native protein are critical to the biological activity of an antagonist and which amino acids should be altered in order

to obtain an MCH antagonist. Without this type of guidance, the skilled artisan does not have a reasonable expectation of making and obtaining a protein that would function as an MCH antagonist. The specification fails to provide even a working example, and as stated above, the indicated preferred embodiments would appear to be agonists rather than antagonists, absent evidence to the contrary. One may argue screening for bioactivity could be done, however, this is basically a "wish to know" and the standard for an enabling disclosure is not one of making and testing. In so far as the instant claims encompass a polypeptides that have yet to be identified, specific case law bears on this issue: Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd., 18 U.S.P.Q. 2d, 1016, held that;

> "A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and describe how to obtain it. *See Oka*, 849 F.2d at 583, 7 USPQ2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated."

The fact pattern is directly analogous in that what is claimed are methods of using polypeptides that have yet to be isolated or characterized for the activity recited in the application and thereby constitutes a "wish to know" rather than a reduction to practice, absent evidence to

the contrary. The decisions of *In re Fisher*, Amgen Inc. v. Chugai, and *In re Wands* have been relied upon by the court in a recent CAFC decision, Genentech, Inc. V. Novo Nordisk, 42 USPQ2d, 100 (CAFC 1997) because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of the claims must be based upon the predictability of the claimed subject matter and no on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not without actually making and testing them, then the instant application does not support the breadth of the claims.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites "A method of inhibiting eating appetite, ...". It is not clear if the method intends a method of inhibiting eating *and* appetite or a method of inhibiting "eating appetite"

(wherein "eating" is an adjective). If the former is intended, the claim should be amended to insert a comma following "eating". If the latter is intended, Applicant may want to delete the word "eating".

Claim 8 recites "MCH". The claim is indefinite because there is no indication of what "MCH" stands for. The art is replete with new proteins, growth factors, therapeutic agents, all with new and inventive names which lend themselves to shorter abbreviations. Upon the first occurrence of the use of a term, the claims should spell out what is intended by the abbreviation; i.e. melanocyte concentrating hormone.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,126,332 (Ohta et al.).

Ohta et al. disclose a method of inhibiting eating and appetite in a subject by administering a composition comprising casein and water-soluble dietary fiber (see claims). The instant claims require the administration of an antagonist of MCH, wherein the instant specification defines an antagonist of MCH as "agents which result in an inhibition of feeding behavior". Therefore, the

composition of Ohta et al. meets the limitations of the instant claims as being an MCH antagonist. Ohta et al. teach the administration to a human (see Example 7 at column 6). Claim 10 requires the diagnosing of the subject for being at risk for any eating disorder, however, Ohta et al. further identify that subjects suffering from diabetes mellitus are at risk and need to be treated by reduction in diet (see column 1, line 44), therefore, this limitation is met by Ohta et al.

11. Claims 8-12 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

The instant claims are directed to methods of inhibiting eating appetite or the gain of weight in a subject by the administration of an effective amount of "an antagonist of MCH". The instant specification defines an antagonist of MCH as being anything that inhibits eating appetite or the gain of weight. Therefore, the claims are directed to a method of inhibiting eating appetite or the gain of weight by anything that inhibits eating appetite or the gain of weight. The public has been practicing the claimed method for hundreds of years in that the eating of low calorie food or reducing the intake of food will inhibit the gain of weight. Furthermore, the drinking of water has long been established as reducing appetite and resulting in inhibition of weight gain. Therefore, the claims are rejected in that the claimed method has been in public use prior to the filing of Applicant's invention, absent evidence to the contrary. Applicant should note that this ground of rejection could be avoided by placing some structural limitations on what is to be considered an MCH antagonist.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohta et al..

The disclosure of Ohta et al. is provided above. Ohta et al. does not explicitly indicate that the composition should be administered in a second dose. However, one of ordinary skill in the art at the time the instant invention was made would readily have recognized that the composition of Ohta et al. would need to be administered in multiple doses, such as before a meal in order to be effective. The composition is a food composition and because humans eat at least once a day, the food composition would need to be administered at the time of feeding, absent evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices

published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 20, 2000

CHRISTINE SAOUD
PATENT EXAMINER
Christine Saoud